MedSun
Medical Product Safety Network

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 250 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions: **http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM510219.pdf**

510(k)s Final Decisions: **http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm509775.htm**

In Brief

As of July 27, 2016

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

AVEA Ventilator by CareFusion: Class I Recall
(July 28, 2016)
CareFusion is recalling the AVEA Ventilator because of a faulty fuse on the ventilators' alarm board, which may cause the ventilator to unexpectedly shut down. If the ventilator shuts down, a patient may not receive necessary oxygen.

Angiodynamics Soft Vu Omni Flush Angiographic Catheter by Stryker Sustainability Solutions (formerly Ascent Healthcare Solutions): Class I Recall
(July 22, 2016)
Device recall due to reports of separation of the tip of the catheter from the main body. Tip separation leads to loss of device function, possible surgical intervention to retrieve a separated segment, or other complications such as blocking blood flow to bodily organs.

INRatio and INRatio2 PT/INR Monitor System by Alere: Recall
(July 12, 2016)
Although Alere is confident that the software enhancements it developed and submitted to the FDA at the end of 2015 effectively address this issue, the FDA notified the company that it believes the company's studies do not adequately demonstrate the effectiveness of the software modification and advised Alere to submit a proposed plan to voluntarily remove the INRatio device from the market.

HeartWare Ventricular Assist Device (HVAD) Batteries by HeartWare Inc.: Class I Recall
(June 29, 2016)
HeartWare Inc. is recalling the batteries because they may lose power prematurely due to faulty cells. If the HVAD system is not connected to an additional power source shortly after the system sounds an alarm indicating a low battery level, the pump will stop working and the patient may experience serious adverse health consequences.

Draft Guidance - Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

In a recently posted Federal Register notice, FDA is notifying stakeholders that we are seeking comments on a draft guidance titled - Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions.

Once finalized the guidance is intended to provide clarity for FDA staff and industry regarding the benefit and risk factors FDA may consider in prioritizing resources for compliance and enforcement efforts to maximize medical device quality and patient safety. Although product availability and other medical device compliance and enforcement decisions are generally fact-specific, FDA believes that consideration of the factors listed in the draft guidance, when relevant, will improve the consistency and transparency of those decisions and that a shared understanding of benefit and risk will better align industry's and FDA's focus on actions that maximize benefit to patients, improve medical device quality, and reduce risk to patients. In addition to evaluating scientific and clinical data, the FDA may also consider the patient perspective and other real world data when determining a device's safety profile.

The FDA also believes the use of this information by medical device companies in their own benefit and risk assessments may help them to better determine whether to initiate a recall to correct a defective product or remove it from the market. The guidance comment period is open until September 14, 2016.

Medical Product Safety Network (MedSun) Final Survey Report
Topic: Syringe Pump Survey
July 2015

Introduction

Syringe pumps are a type of infusion pump used to deliver fluids such as medications, nutritional liquids such as breast milk or formula, and blood/blood products to patients. They are used extensively in the care of children, infants and newborns in areas of the hospital such as Pediatric Intensive Care Units, Neonatal Intensive Care Units and Emergency Departments.

In 2015, in response to medical device adverse event reports received from hospitals and review of professional literature, FDA staff from the Center for Devices and Radiological Health wanted to learn about experience with syringe pumps from the perspective of hospital-based Pediatric Intensive Care Unit (PICU) and/or Neonatal Intensive Care Unit (NICU) nurses who use them extensively. This effort was a part of FDA's ongoing efforts to ensure the safety and effectiveness of medical devices.

FDA staff recruited PICU/NICU nurses to respond to a questionnaire concerning their use of syringe pumps and especially their experience, if any, related to problems with delay of therapy (such as for delivery of pain medication or blood pressure medication) when syringe pumps were used with low volumes of medications infused at low rates (defined as less than 1 or 2 mL of medication per hour). The questions covered the respondents' clinical background, the types of syringe pumps and accessories for those pumps (e.g., tubing and syringes) that were used recently by the respondents, how long they had used the pumps, training provided for use of the pumps especially with low volumes of medications, the accessibility and use of Instructions for Use/Quick Reference Guides for the pumps, preparatory steps taken for activities such as priming the tubing, whether they had experience with and/or knowledge about delay of therapy issues using syringe pumps at low volumes, and comments concerning syringe pump use.

Methodology

A small sample of hospitals that participate in FDA's Medical Product Safety Network (MedSun) was selected for survey recruitment based on their size, location and likelihood of using syringe pumps for the care of pediatric and/or newborn patients. From late June to late July 2015, 7 NICU nurses were interviewed, and 2 additional nurses responded in writing. Two of the nurses who responded indicated that they were considered PICU/NICU nurses because their work was with pediatric patients as well as with newborns. In total, 9 responses came from nurses in 8 hospitals across the U.S. Although one of the hospitals was a pediatric hospital, the other 7 were acute care hospitals that included Neonatal Intensive Care Units (whether or not they provided any other pediatric care). The sites included two university-based hospitals. The hospitals that responded all had at least 150 beds, with two being large (over 400 total beds); the hospitals had NICU units of approximately 20 to 75 patients each, and at least two hospitals had more than one NICU.

Overview of Responses:

Level of Clinical Experience of the Respondents:

The majority of respondents had at least 7 years of NICU-based clinical nursing experience, with at least two having over 30 years of NICU and/or combination NICU/PICU nursing experience. One respondent was a

Clinical Educator for her hospital's NICU staff. In some cases, NICU managers and/or other nursing leaders participated in the calls; these calls involved 2-4 hospital staff, and always included at least one NICU nurse as the primary respondent.

Syringe Pumps Used:

In most cases, the respondents indicated that their NICUs used one of two syringe pumps made by two different manufacturers. In some cases, while the syringe pumps were used for a wide variety of medications and other fluids (such as antibiotics, epinephrine, norepinephrine, normal saline, and blood products), other pumps were used for feeding. In one case, one manufacturer's product was used for NICU syringe pump use, whereas a different manufacturer's syringe pump was used when the patient was being transported.

Two hospitals indicated that they used color coding systems to distinguish between their syringe pumps used for feeding and syringe pumps used for medications/blood/other non-feeding products in order to avoid dangerous misconnections (such as infusing breast milk into an IV line). Notably the color for the pumps/tubing/syringes for feeding was orange in one hospital and purple in another hospital that used the color coding, indicating that the color coding is not consistent across hospitals in the US. One hospital indicated that they have a standard practice of having the syringe pump used for feeding located at a certain end of the patient's bed, whereas the syringe pump for medication infusion is always supposed to be located at the other end of the bed.

One nurse interviewed said that she thought her hospital was going to switch from use of one manufacturer's pumps to another manufacturer's pumps because they wanted to align with what they considered to be a high percentage of NICUs in the nation that use that pump, but they would research the pumps first.

One hospital's respondents indicated that they had moved away from one manufacturer's pump to another's pump approximately 3 months before the interview due to problems they experienced with delay of therapy with low volumes of medication. (This hospital was changing their choice of pump in the opposite direction as compared to the hospital mentioned above.) They indicated that the manufacturer's staff came on site for one week to troubleshoot the problem without success, and then the hospital made the decision not to use the syringe pumps in the Critical Care (including NICU), OR, or ED settings, although they are still using them in acute care areas of the hospital. The troubleshooting effort involved investigating any problems with the manifolds, using different manifolds, removing the manifolds, using a different sensing disc, using catch up valves for vasoactive drugs, and using smaller syringes. This hospital had been using the priming feature on the pump (rather than priming manually as described by nurses in other hospitals).

Availability and Use of Instructions for Use (IFU) and Quick Reference Guides:

Although many of the nurses indicated that there were Instructions for Use and/or a Quick Reference Guide available in their NICU, generally they did not read them or refer to them. One nurse indicated that the new nurses use these materials until they become experienced, while another nurse indicated that once their NICU staff learn to use the pumps, they do not use these materials. In some interviews, the nurses indicated that they did not have Instructions for Use or Quick Reference Guides available.

Training concerning Use of Syringe Pumps with Low Volumes of Medications:

The respondents were asked to describe the types of training they had received for use of the syringe pumps. The training may have been provided by manufacturer representatives, hospital staff or both. The respondents described the types of training provided by manufacturers or by hospital "superusers" when the pumps were purchased. Staff who joined the NICU staff several years after the purchase indicated that they received less training or no training from the manufacturers or from hospital clinical educators.

One hospital that had experienced significant problems with one syringe pump said that they had received "little information" from the manufacturer about infusion at low rates, and that their representatives had "trouble defining low rates," using less than 3 mL/hour in some cases and less than 1 mL in other cases (with similar discrepancies in some of their written materials according to this hospital).

Generally the respondents who used another manufacturer's pumps indicated that they had received some training concerning use of that syringe pump with low volumes of medications, and they described what that training included (e.g., checklists, information about using the smallest syringe size that can be used when infusing low volumes, reducing the tubing length and diameter to accommodate low volume infusions, and information about priming on the pump).

Preparation Steps/Set-up Procedures:

Most of the nurses included in the survey indicated that they prefer to prime the tubing for the fluids to be infused using a manual procedure rather than use what they consider to be a more time-consuming process of priming the tubing using the syringe pump priming feature. They said they found the manual priming to be very quick (taking only seconds) and some nurses indicated they had more confidence in the priming if they had done it themselves.

Several nurses described the practice of two pumps running simultaneously in preparation for changeover of the patient's tubing to avoid problems with delay of therapy. One nurse indicated that this had been a very common practice by their NICU nurses, some of whom had first-hand experience with problems of delay in therapy, when they used one syringe pump but that the practice had been used less often since they changed to another pump and "staff had more confidence" in the timing for the delivery of the low-volume medications. (They still use the two pumps for very critically ill patients who cannot tolerate a delay.) Note that a NICU nurse with over 30 years of experience who worked at another hospital said that she used the 2-pump method frequently to ensure smooth transitions when tubing was being changed. Other nurses pointed out workarounds to avoid problems when tubing is not vertically aligned and the need to "prop up" pump tubing with gauze in some cases.

The nurses described steps they used to minimize the chances of delay in therapy. These steps included using syringes that are as small as possible to optimize medication delivery (coordinating with Pharmacy to provide a smaller pre-filled syringe as needed), making sure that they are using the right size of tubing for the situation, minimizing the distance between the pump and the patient, and using the 2-pump system described above when needed to prepare for periodic changeover of the patient's tubing.

Two hospitals described detailed charts that the nurses received to determine the proper doses for the weight of the patient that had been developed for their hospitals. In one case, the nurse provided examples of these charts, which had been developed by an interdisciplinary team of healthcare professionals specifically for their hospital, to FDA staff.

Experience With/Knowledge of Possible Delay in Therapy with Low Volume Medication Infusions:

Three of the nurses interviewed said they had experienced or seen first-hand a problem with delay in therapy when low volumes of medications were being infused using syringe pumps. Of the remaining respondents, approximately one-half had not experienced cases of delay in therapy but had heard/read something about the problem, and the other half said they did not know about the potential for delay in therapy with low volumes of medications.

Lengths of Tubing Used/Sizes of Tubing Used and Types and Sizes of Syringes Used:

Generally the respondents said that they used tubing that was either 59 inches long or 60 inches long, although other lengths were available as needed. Although the questions did not ask about specific diameters for the tubing, at least one hospital volunteered that they used microbore tubing with their syringe pumps. Another nurse provided the following specifics concerning tubing that her hospital used:

> (We use) 0.28 mL tubing for intermittent medications, (and) 0.8mL tubing with stopcock for continuous medication drips used on syringe pumps - both of these with a filter. Blood products use 2mL tubing with no filter.

Respondents said they used several sizes of syringes depending on the specific needs (generally sizes 1, 3, 5, or 10 mL for specific medication/feeding uses, and larger sizes such as 20 and 30 mL for use with blood/ blood products). A specific manufacturer's 1 mL syringes presented problems when used with the pumps at certain sites, as shown below:

> We have (experienced delay of therapy) a few times …with our 1mL syringes for IV that do not work well on the specific pump we use. They alarm frequently "not reading"; many times we push the medication and put a flush …Other issues we have had were with our continuous sedation drips. If a slow rate was used, which is usual, we have had the fluid back up in the line and see blood backing up. The pump was infusing at 0.15 -0.5mL per hour. We have since changed to different filters (and) that should help.

There were consequences for the baby when this happened, as shown below:

> This baby did not receive his/her medication as it was backing up blood in the tubing. The baby was agitated, with higher pain scores. Sometimes we have to elevate our tubing with blankets (or) gauze, if they are running at low rates of infusion, as the (parenteral nutrition) or large volume fluids will back up in our IV tubing of our syringe pump fluid.

The nurses interviewed indicated that they generally used one manufacturer's syringes with their syringe pumps, again in various sizes, and generally used a standard size syringe for drips (which differed among the hospitals in the survey). Some sites used one manufacturer's syringes on their NICU feeding pumps and another manufacturer's syringes for syringe pumps used in patient transport. The choice for the specific tubing and other accessories often depended on the hospitals' purchasing policies for such products, as well as compatibility with the pump.

Although one hospital indicated that their NICU staff sometimes transferred fluids such as medications into smaller syringes in the NICU as needed, most of the nurses interviewed indicated that if they needed a change to a different size of syringe (e.g., smaller syringe), their Pharmacy staff would provide it. One nurse indicated that they have a Pharmacy representative located in and assigned to the NICU. Another site indicated that their NICU nurses (rather than Pharmacy, as was generally the case) sometimes transferred fluids from larger syringes to smaller syringes in the Unit.

Other Comments:

One hospital that had experienced problems with a syringe pump mentioned that they had received a Product Information Safety Sheet from the manufacturer that they could forward to FDA, and an article about the pulsating action of various brands of syringe pumps that they could also send.

Several of the NICU nurses indicated how much they liked using syringe pumps with their patients, and the significant advantages they found with some of the pump features such as the drug library dose error reduction software and settings for NICU use.

One NICU nurse mentioned the difference in the number of decimal places for settings on one manufacturer's syringe pump (display shows to one-thousandth or 0.00x mL/hour) vs. another manufacturer's(display shows to one one-hundredth mL/hour or 0.0x).

Summary

The respondents to this survey provided a great deal of detailed information for FDA's research into the use of syringe pumps at low rates. Generally the NICU nurses that we spoke with did not make use of the Instructions for Use or Quick Reference Guides except perhaps in the early weeks of learning to use a new syringe pump or for troubleshooting purposes. They indicated that for some pumps, they received relatively

little formal training but instead depended on their own experience and the experienced nurses in their units to help them address problems that came up with the use of syringe pumps.

Providing information about the possible problems with syringe pumps when they are identified emerged as an issue that needs to be addressed. A hospital that had experienced significant problems with one manufacturer's pump expressed concern about other hospitals serving pediatric patients that used that pump not knowing about the possible problems such as delay of therapy with low volume infusions. In contrast, sites that had not directly experienced problems with delay of therapy related to low volume medications delivered through syringe pumps indicated that the nurses who saw those problems "may not be priming the tubing correctly" or otherwise may be making errors in their set up or operations of the pumps. Some of these hospitals reported that they practiced the dual pump method when changing out medications for hemodynamically unstable patients.

The survey provides information that may lead to further data collection regarding problems with specific syringe pumps and the steps that hospital staff take to avoid them or address them if they occur.

Survey Limitations

Although the findings add to FDA's knowledge of hospitals' purchases and uses of syringe pumps, there are several limitations to the survey methodology. These include the small convenience sample of respondents and the challenge with obtaining specific product information from hospitals. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during July 2016. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

Special Note:

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as less than 21 years of age

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Device	Manufacturer	Problem
Cable Brand: High Frequency Monopolar Cable Cat #: 502-990-300	Stryker Endoscopy	The monopolar cord sparked a flame at closes to the connection to the flame.
Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System Brand: BD Phaseal Connector Lot #: 1601001 Cat #: 515202	BD	Chemo orders previously checked by two chemo RNs. Consent verified. 168 mg IV Etoposide double checked by two chemo competent RNs, drug vs original order vs patient using three positive patient identifiers. Appropriate chemo precautions and PPE utilized. Right double lumen PICC line flushed and aspirated with positive, brisk blood return. RN stayed with patient for first five minutes of infusion. Patient tolerating infusion without complication. After approximately 55 minutes, RN came in to check on patient. Patient complained that her pillow that her right upper extremity (RUE) was resting on (extremity with DL PICC) "esta mojado" (is wet). RN felt wet pillow and realized it could be chemotherapy - immediately stopped the Alaris pump. RN aspirated from the lumen where Etoposide had been infusing - positive brisk blood return present. RN then flushed from downstream port - some saline leaked out between the blue, luer lock blue clave and the smaller Phaseal. RN turned off pumps and got spill kit and called charge RN into room. Hydrogen peroxide ordered. Charge and bedside RN utilized chemo spill kit and disposed of soiled linen. Patient immediately washed affected skin with soap and water. Then washed with hydrogen peroxide. Linens changed. RNs estimated approximately 20-50 cc lost Etoposide via spill. PICC line dressing, caps and tubing changed.

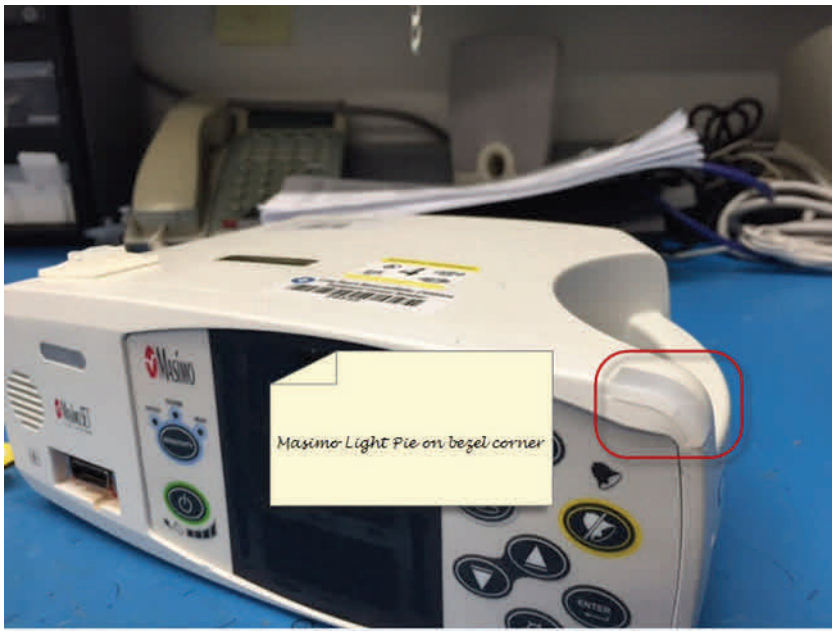
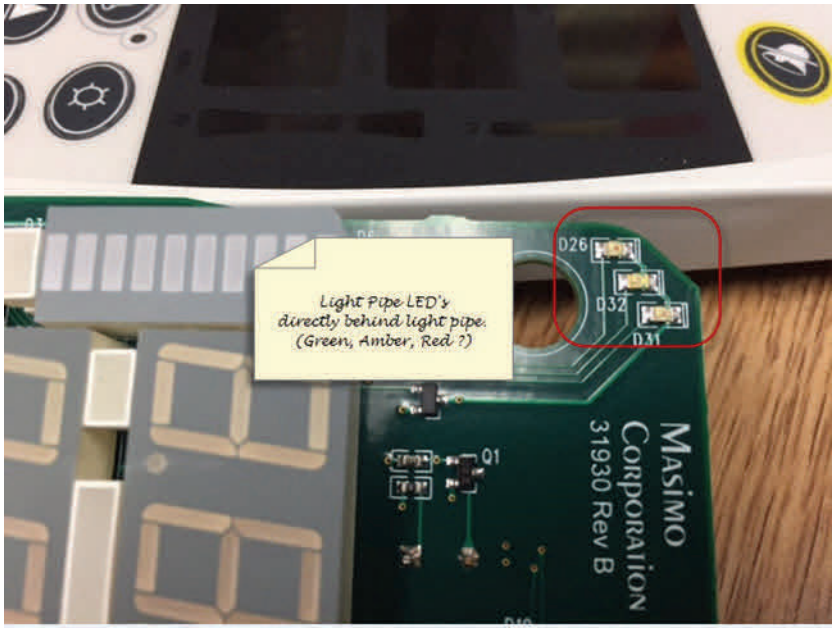
Apparatus, Autotransfusion Brand: Cobe Continuous Autotransfusion System	Terumo BCT	Machine was processing at a slow rate on emergency and the blood seemed to be visually not of good quality. The Anesthesia Tech performed QC with the Hct coming back under 20%. 2 additional bags were tested with the result of a low hemocrit. It was determined that the blood that was being processed was not quality. The blood that was processed was disposed of. There was an issue with how the blood was being processed. We called the rep and he did not know what the issue could be. It could be the sensor not working appropriately or an issue with the disposable. Wasted 6 bags of Cell saver blood. The case proceeded and they stopped using cell saver. One of the technicians reloaded the cell saver with a new disposable and we processed some of the blood. Cell saver operated fine with a QC Hct at 60%. We did not return the blood. Cell Saver had been used 4 times prior without issue and Hct above 70%. Patient did not require a blood transfusion, the cell saver blood was not used either.
Computerized Robotic Surgical System Brand: Tip Cover Accessory Lot #: M10160413 Cat #: 400180	Intuitive Surgical, Inc.	The da Vinci S tip cover accessory failed. This is the second time an accessory tip has failed. The manufacturer is aware and looking in to their product.
Cook Biliary Drainage Catheter Brand: Biliary Drainage Catheter With Mac-loc Model#: G13355 Lot #: 5841873 Cat #: ULT12.0-38-40-P-CLBS-26-RH	Cook	Drain broke after patient arrived home, per patient they hadn't done anything unusual. Fluid stopped draining. Patient needed to return to the OR for replacement.
Device, Digital Image Storage, Radiological Brand: Sdc3 Video Capture Device Digital Documentation Model#: SDC3	Stryker Endoscopy	During surgery, the SDC video capture device was used to save numerous photos of the surgery. Photos are used to document procedure and become part of the patient's medical record. Photos may be needed to get reimbursement for some procedures. At the end of surgery, it was discovered that most of the photos were not captured. We have been having an abnormally high failure rate of the DVI video input boards on these units. In one area, 7 out of 8 have failed. There have been several documented delays during surgery caused by failures of the recording device. Not related to the DVI input, we have also had problems with the software becoming corrupted if the unit loses AC power, like during the emergency generator test. In most cases this can be corrected by reloading the software. Software version is 1.3.1. We believe the version hasn't changed since we bought these. We think this is mainly a hardware issue with the DVI input board.

		the right groin, low grade fevers, pain, chills and tachycardia. A surgeon consulted and the patient was brought to the operating room for irrigation and debridgement of the right groin. Surgical findings were that there was a retained Mynx closure device in a subcutaneous abscess. It did not appear to track to the artery itself. The Mynx closure device was removed. (The Mynx closure device is generally resorbed by the body within 30 days.) Final groin culture result showed moderate grown of STreptococcus Group F; moderate gram positive cocci, moderate gram negative coccobacilli. Pathology report findings: Gross - Infection closure device Mynx plug: Two tan/pink soft tissues with blood, 0.5 and 1.2 cm in greatest dimension Patient was discharged after six days of hospitalization to a transitional care facility.
Device, Hemostasis, Vascular Brand: Perclose Proglide Smc System 6f Cat #: 12673	Abbott Vascular	Patient in Cath Lab for complex/high risk coronary stenting procedure and impella used during the procedure to support patient. Patient had a 14FR 30cm Cook sheath. When the procedure ended, a Perclose 6FR device was deployed by the doctor for arterial closure, but the deployment was unsuccessful. As a result of this failure of the Perclose to deploy, the doctor inflated a PTA balloon in the left common femoral artery and inflated to maintain hemostatis. A vascular surgeon was consulted urgently and arrived promptly. The surgeon noted the ProGlides failed and wire access was lost in the patient's ipsilateral groin. The surgeon placed a 13 mm Viabahn (covered peripheral stent) in the right common femoral artery resulting in cessation of the bleeding. The right groin site was monitored for 30 to 40 minutes post Viabahn deployment with no further bleeding. During this time, the blood bank was notified of need for 2 units packed cells and 2 units of O negative blood released and infused in Cath Lab. (Patient had received Angiomax during the procedure so platelet function was impacted and the patient was at higher bleeding risk.) Hemostatis was obtained before leaving the cath lab and patient was transported to the nursing unit. The Perclose device and packaging was discarded.
Device, Neurovascular Embolization Brand: Microvention Coil Lot #: 160314V5	MicroVention Costa Rica S.R.L.	The coil would not detach. Returned to manufacturer. Response from IR Radiologist: The coil failed to detach, so it was withdrawn from the patient. The remainder of the case went well, with additional coils placed without incident. No harm to patient.
Forceps, Biopsy, Non-electric Brand: Alligator Jaw Step Model#: FB-211D Lot #: 58K	Olympus America, Inc.	A set of disposable biopsy forceps malfunctioned/broke while obtaining tissue specimens from inside the patient's lung. Once able to remove the forceps from within the bronchoscope - it appears that all the mechanical parts are present. When assessing the instrument at the procedure cart it was noted it was not functioning properly and 2 wires would stick out way past the forceps. This set of forceps and all of the rest of the forceps with this lot number (58K) were taken out of service and placed in an isolated bag.

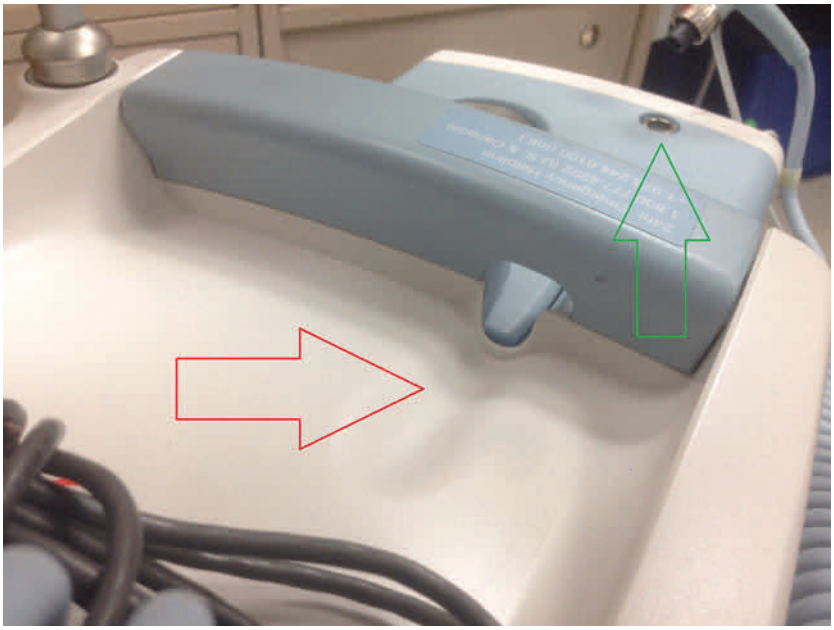
Hemodialysis, Catheter Brand: Schon Xl Acute Hemodialysis Catheter Lot #: MHDA660 Cat #: 10801702	AngioDynamic	A hemodialysis catheter was inserted into a patient in Interventional Radiology and that patient was then sent to the dialysis unit. The dialysis unit reported that the catheter was leaking. The patient was sent back to interventional radiology and saline was injected into the catheter. Holes were found at the hub. A second catheter was placed and saline was injected into this one. Again, holes were observed near the hub of the catheter. A third catheter was placed and saline was injected and no holes were seen. The second catheter that was placed was saved for evaluation and return to the manufacturer.
Infraclavicular Nerve Block Catheter Brand: Cadd Yellow-striped Administration Set Lot #: 2021-03 46X196 Cat #: 21-7339-24 Other #: GTIN: (01) 10610586027307	Smiths Medical ASD, Inc.	A status-post car accident sustained a serious right arm degloving injury from shoulder to wrist. Pain Service had regional block placed for post-op pain management. Started out with an intrascalene catheter, and changed to intraclavicular with Bupivacaine 0.25% continuous infusion. The device was changed out to an infraclavicular catheter (the administration set used to have a label with black bold print indicating that it was an epidural catheter and the currents sets DO NOT. The yellow stripe becomes visible if you turn the tubing a certain way and the previous tubing used to be stiffer, where this tubing is more pliable. Had a label come with the set, this may have prevented the mix up. The male luer is compatible with the extension sets that are used with the regular IV tubing sets) and when they went to connect it to the Bupivacaine it was found that the Bupivacaine had been connected to her periperal IV on the left arm. Patient was mildly lethargic, tachycardic at 110 bpm, alert and oriented x3. A suspected local anesthetic systemic toxicity (LAST) protocol was initiated. EKG showed ST with no AV/SA nodal block. A 20% intralipid infusion was bolused, followed by a continuous infusion. The patient was transferred to ICU for closer monitoring. The patient was transferred back to floor status the following day without any harm noted.
Infusion Pump, Syringe Brand: Medfusion 4000 Model#: 4000 	Smiths Medical ASD, Inc.	No HARM: I called Smith Medical to inquire as to whether or not anyone has ever reported a child actually squeezing the lever on the side to remove the syringe from the device and manually infuse the medication. The pump did alarm (syringe issue?) but the child had already pushed the medication in by himself.
Needle Brand: Power-loc Ez Port-a-cath Needle 20g X1. 0" Model#: SHW20-100Y Lot #: REAQ0332 Cat #: SHW20-100Y	Bard Access Systems, Inc.	The nurse tried to access the patients port-a-cath port with a port-a-cath needle. When the nurse tried to insert the needle into the patient's port, the needle folded over in half and was unusable. Another needle was pulled and access in patient's port was successful. Subsequent test were done to try and duplicate the event and the test needle would not bend even with significant force. Not sure why the initial needled bent in half.

Device 1: IV Pump Brand: PCA Cadd Solis Pump **Device 2:** Tubing, Fluid Brand: Cadd Solis Tubing Cat #: 21-7052-24	Smiths Medical, Inc. Smiths Medical, Inc.	Potential epidural pump malfunction. The nurse reported that the amount left was less than the amount wasted when the cartridge was changed. According to the pump, there were 7.1 mL left in the cartridge. But when disconnected and wasted, 22 ml were found to be left. This equates to 14.9 ml. This could lead to observed or perceived increased needs for pain control and subsequent overdosing of opiod during transition to alternate form (oral) medication delivery. It was noted, however, that this patient's pain was adequately controlled. Patient had IV hydromorphone orders for breakthrough pain, but no prn hydromorphone was given per the medication record. Per another nurse, this had happened at the last cartridge change as well. Nurse indicated was unsure if patient has been underdosed due to pump malfunction. The pump was exchanged. Biomedical Engineering inspection of the pump, PCA CADD SOLIS 2110: Biomed tested the unit following the manufacturer's "annual inspection and testing procedures." Unit passed all tests and all values were in spec. No problem was found with this unit.
Device 1: IV Tubing Extension Brand: Cadd Extension Set Cat #: 21-7106-24 **Device 2: IV Tubing Extension** Brand: Cadd Extension Set Cat #: 21-7106-25	Smiths Medical Inc. Smiths Medical Inc.	This report is a continuum of a previous report regarding Smiths CADD Solis pump under-delivery. Testing was conducted by a biomedical technician and pharmacist of the "standard" tubing "with" and "without" the filter. The theory of filter drag with the high rate of fluid administered during the short bolus period was tested. Testing was conducted using a pump that was associated with the last reported error. The readings simulate on demand only of a 0.4 mg dose with a 0.2 mg/ml hydromorphone. The averages of the testing are as follows: Microbore CADD Extension Set (Ref # 21-7052-24) With Filter - Intended Admin. Volume (ml) = 2; Average Admin. Volume (ml) = 1.628; % Variance = -18.63%; Avg. discrepancy with 50ml cassette of demand only dose (ml) = 9.31. Without Filter - Intended Amin. Volume (ml) = 2; Average Admin Volume (ml) = 1.958; % Variance = -2.13%; Avg. discrepancy with 50ml cassette of demand only dose (ml) = 1.06. "Standard" CADD Extension Set (REF#21-7106-24) With Filter - Intended Admin Volume (ml) = 2; Average Admin Volume (ml) = 1.960; % Variance = -2.00%; Avg. discrepancy with 50ml cassette of demand only dose (ml) = 1. Without Filter - Intended Admin Volume (ml) = 2; Average Admin Volume (ml) = 2.090; % Variance = 4.50%; Avg. discrepancy with 50ml cassettee of demand only dose (ml) = -2.25. Smiths Medical CADD Solis pumps are used at our hospitals for delivery of epidurals as well as PCAs (patient controlled analgesia). The testing above reflects a high, although reasonable, administration of opioid tolerant PCA bolus dose. In their follow up to the Smiths CADD Solis pump events, one causation theory from Smiths was that there is a filter drag with high rate of fluid administered during the short bolus period (e.g. patient controlled dose in PCA or PCEA). While Smith did indicate they are conducting tests to identify the source(s) of the issue(s), we also conducted testing as outlined above.

Needle Brand: Power-loc Ez Port-a-cath Needle 20g X1. 0" Model#: SHW20 -100Y Lot #: REAQ0332 Cat #: SHW20-100Y	Bard Access Systems, Inc.	The nurse tried to access the patients port-a-cath port with a port-a-cath needle. When the nurse tried to insert the needle into the patient's port, the needle folded over in half and was unusable. Another needle was pulled and access in patient's port was successful. Subsequent test were done to try and duplicate the event and the test needle would not bend even with significant force. Not sure why the initial needled bent in half.
Orthopedic Stereotaxic Instrument Brand: Mako Checkpoint Lot #: W39916-8 Other #: Check Point 3.5mm x 15mm	MAKO Surgical Corp	While attempting to remove check point in acetabulum, the check point migrated further into bone. Fluoroscopy was utilized and the check point identified to have migrated further in the bone at the posterior column. Further extraction attempts were unsuccessful.
Oximeter Brand: Rad-87 Model#: Rad-87	Masimo Corporation	During testing and equipment history review Biomedical Engineering noted excessive failures with our portable pulse oximeter monitor's visual alarms. During alarms, the monitor's Red alarm LED would not flash. The clinical team would respond to the monitor's audible alarm and overhead door light when the monitor alarmed. The clinicians would not report that the RED LED was not flashing. Biomedical review of several monitors noted that the alarm LED was inoperative. Biomedical sequestered all of the affected pulse oximeters and has arranged for factory evaluation and repair. There were no reported patient adverse events. ========== Manufacturer response for Monitor, Pulse Oximeter, Rad-87 (per site reporter) ========== Awaiting follow up by manufacturer. On-site testing by Biomedical confirmed that red LED alarm lamp did not illuminate during alarm event. All other Display activities and audible alerts did function correctly. Biomedical collected 10 additional pulse oximeters with the same failure. All 11 will be sent in to the manufacturer for evaluation and report. These devices are approximately 6 years old. The facility is afraid these might be getting hit (during normal use and transport) on the corner causing these failures. They have been having Light pipe breakages since day one on these monitors. Please see pictures below:

		 
Permanent Pacemaker Electrode <u>Brand:</u> Capsure-fix Novus <u>Cat #:</u> 5076	Medtronic, Inc.	A Medtronic device lead was opened onto the procedural table. The physician noted the screw appeared to show at the end of the lead. The physician retracted and extended the screw, but did like the way it felt so a second lead was implanted in to the patient. There was no known patient harm.

Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene Brand: Vascu-guard Model#: 3213-0108-0011 Lot #: SP16E04-1148522 Cat #: VG0108N	Baxter Healthcare Corporation	Patient was here with a diagnosis of severe left carotid stenosis. Approximately one month ago, he had a technically uncomplicated left carotid endarterectomy. Before closing, the suture line was tested by compressing it with forceps and observing it multiple times. The carotid wall was of normal quality and the suture bites and suture type were appropriate. He transferred from the OR to the CICU at approximately 1140. Approximately an hour after arrival in the CICU the patient complained of neck swelling and difficulty breathing and had increased bleeding from his surgery site. He deteriorated quickly and became unresponsive. The code team started CPR at approximately1310. Despite all efforts the patient died. The surgeon's note states, "The neck incision was opened at the bedside, and pressurized hematoma was evacuated. Significant bleeding was noted, consistent with a disruption of the suture line of the carotid patch." His reason for death is believed to be hypovolemic shock from hemorrhage and airway compromise following a carotid endarterectomy. An autopsy was not requested. Approximately a week and a half ago Baxter issued a Safety Alert for the Vascu-Guard Peripheral Vascular Patch stating reports of intraoperative and postoperative bleeding. The lot numbers listed in that Safety Report matches the lot number of the patch used on this patient. This information was provided to the surgeon who states concern that the patch may have contributed to this patients bleeding and ultimately his death.
Staple, Implantable Brand: Ets 45 Linear Cutter Reload Lot #: l4F17K Cat #: TR45W	Ethicon Endo-Surgery, Inc.	Patient had lap chole for gangrenous cholecystitis. The gallbaldder was friable and immediately perforated with grasping. The neck of the gallbaldder was grasped and retracted anteriorly. Blunt dissection was used to find the cystic duct. It was very thick. The surgeon was able to take down all the surrounding tissue. Due to the thickness of the duct, an Ethicon 45mm vascular load stapler was used. It was clamped down and fired. It did feel like it fired very roughly and when removed there were no staples left on the cystic duct stump, but the stump was transected. At the end of the procedure, the cystic duct stump was coated with Evicel and a drain was placed. Several days later, patient had bilious drainage and required endoscopic retrograde cholangiopancreatography with sphincterotomy with biliary stent placement.
Tubes, Vials, Systems, Serum Separators, Blood Collection Brand: Venoject Multi-sample Luer Adapter Cat #: XX*MN2000OT 	Terumo Corp	The VenoJect Adapter and BD one-use holder were used to draw blood from a central line. When the RN tried to remove the adapter from the central line the adaptor broke leaving a portion of the adaptor lodged into the central line. Multiple RN's attempted to remove the plastic piece and eventually required the use of hemostats to remove the broken adaptor from the end of the line. The patient safety report also stated that This has happened 1 other time in our clinic in the past 3 weeks.

System, Balloon, Intra-aortic Brand: Cardiosave Hybrid	Maquet Medical Systems USA	The Maquet Cardiosave Hybrid Balloon Pump has a poorly designed top panel. The panel is designed such that any liquid that finds its way into this area will be funneled directly into the 14 pin monitor connection site. When saline was applied to this connection site the machine shut down. The top panel is labeled with signage discouraging the placement of IV bags in this area. However in practical use fluid will find its way onto this panel. Even a small amount of liquid will flow directly to the monitor connection site because of the funnel design. This top panel should be redesigned to prevent the flow of liquid into the monitor connection site or a liner should be applied to the top panel to collect liquids and prevent their flow into the monitor connection site. Please see picture below: 
Tubing, IV Fluid Delivery Brand: IV Catheter Extension Set Male Luer Lock Adapter Cat #: 2N1194	Baxter Healthcare Corporation	Pediatric Nurse entered the patient's room to respond to a low blood pressure alarm via the arterial line. Nurse found patient in her crib lying in a large pool of blood. Nurse clamped the arterial line and called for help. MD and nurse found the arterial line tubing leaking from a crack. They were able to replace the broken tubing and stop the bleeding. The appropriate medical interventions were followed regarding loss of blood. A similar event occurred next morning where nurse found broken arterial line tubing leaking blood from the patient. The estimated amount of blood loss was small. The appropriate medical interventions were followed regarding loss of blood. Both patients are now ok. Possibly lot# UR16B25120

Ventilator, Continuous Use, Facility Brand: Hamilton -mr1 Model#: MR 1 161010	Hamilton Medical AG	An intubated patient was being positioned in the MRI scanner when the respiratory therapist accidentally moved the MRI conditional ventilator and cart too close and it was pulled into the side of the core of the MRI system. The ventilator had an oxygen tank on it that was marked "MRI Safe." Staff pulled the vent away from the core and the vent continued to function. The patient continued to receive ventilation and vital signs were normal - there was no adverse outcome for the patient. The vent showed a fan failure alarm, but continued to delivery breaths. The oxygen tank was taken out of the room as a precaution. After the scan was completed, the ventilator was brought to Biomedical Engineering for an evaluation. Follow up: The respiratory therapist received education refresher from manager. Biomedical engineering reported that the vent alarming, "vent failure" and TESLA Spy indicating red condition. Talked to tech support. Ordered parts. It appears as though the respiratory therapist pushed the vent and rolling stand too close to the bore. Checked tank, cart and vent for ferrous metals with a magnet. Very small reaction around PB quick connect and back of vent. Recently replaced cooling fan to resolve "fan failure" issue. Several days later began performance certification. Unit failed battery valve tests and tightness tests. It was determined that we would send unit to the manufacture for complete check out.

Links to FDA/CDRH Databases and Other Information Sources

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm119185.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/cdrh/medicaldevicesafety/
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: http://www.fda.gov/medsun/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm
This database contains the most recent manufacturer warning letters.

To access additional August 2016 newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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